UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/631,470	04/15/96	BROD	D5716CIP2

EXAMINER: S

ART UNIT: 1302 | PAPER NUMBER: 5

A3M1/1217

BENJAMIN ADLER
GILBRETH AND ADLER
8011 CANDLE LANE
HOUSTON TX 77071

DATE MAILED: 12/17/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/10/97.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Notice of Informal Patent Application, PTO-152

X Notice to Comply with Requirements for Sequence Disclosures.

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

★ U.S. GPO: 1996-410-238/40050

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

2. Claims 1-4, 6-11, 13-20 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Cummins, Jr. (U.S. Patent 5019382).

See col. 4, lines 19-36, col. 5, lines 50-55, col. 6, lines 12-26, col. 13, and the claims. Such disclosure meets the claims.

3. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. Claims 5 and 12 are rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382). The disclosure is the same as above as discussed for claims 1 and 8. The patent does not disclose an alternate day dosing. However, it does show that a daily dosage is possible, as a single dosage or as divided and administered in a multiple daily dose regimen. The reference also teaches a staggered regimen of 1-3 days per week or month as an alternative to daily dosing. See col. 5, lines 50-55. With such a flexibility as taught by the reference, and since it is common knowledge in the art to employ such a regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc., it would have been obvious to one of ordinary skill in the art to adopt an alternate day dosing and administer IFN as shown by Cummins for MS.

5. Claims 1-20 are rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382) in view of Shibutani et al. (Iyakuhin Kenkyu, vol. 18(4), pp. 571-82, 1987).

The disclosure for the patent is as discussed above. The whole range of dosages claimed by the instant invention is not shown. However, the Shibutani abstract indicates

that IFN toxicity studies with rats showed that it was tolerated well. Therefore it would have been obvious to one of ordinary skill in the art to administer dosages higher than that shown in the patent with the reasonable expectation that such doses would not produce toxicity side-effects in humans. It would also have been obvious to employ such an alternate day dose regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc.

6. Prior to taking up this case for examination, the examiner had contacted applicant, and reminded him as per 37 CFR 1.56 to submit references in the specification at pages 66-67 for proper consideration and complete examination of this invention, particularly since these references were inaccessible to the examiner. Since no references have yet bee submitted, applicant is once again urged to submit these references cited at pages 66-67 for proper consideration and complete examination of this case.

Any inquiry concerning this communication should be directed to Examiner C. Sayala at telephone number (703) 308-3035. Any inquiry of a general nature or relating to the status of this application should be directed to the Group

receptionist whose telephone number is (703) 308-0196. The group fax number is (703) 305-7401.

C. Sayala
Primary Examiner
Group 1800.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). **(SEE EXAMPLE 31)**. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applicantions Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

CHHAYA D. SAYALA
PRIMARY EXAMINER
GROUP 1300

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

2. Claims 1-4, 6-11, 13-20 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Cummins, Jr. (U.S. Patent 5019382).

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3. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. Claims 5 and 12 are rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382). The disclosure is the same as above as discussed

for claims 1 and 8. The patent does not disclose an alternate day dosing. However, it does show that a daily dosage is possible, as a single dosage or as divided and administered in a multiple daily dose regimen. The reference also teaches a staggered regimen of 1-3 days per week or month as an alternative to daily dosing. See col. 5, lines 50-55. With such a flexibility as taught by the reference, and since it is common knowledge in the art to employ such a regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc., it would have been obvious to one of ordinary skill in the art to adopt an alternate day dosing and administer IFN as shown by Cummins for MS.

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The disclosure for the patent is as discussed above. The whole range of dosages claimed by the instant invention is not shown. However, the Shibutani abstract indicates that IFN toxicity studies with rats showed that it was tolerated well. Therefore it would have been obvious to one of ordinary skill in the art to administer dosages higher than that shown in the patent with the reasonable expectation that such doses would not produce toxicity side-effects in humans. It would also have been obvious to employ such an alternate day dose regimen instead of

continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

7. Claims 1-12 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification for terms "immediately upon" oral administration. The specification is limited to and shows that the cytokine was ingested and that it was orally administered.

8. Applicant's arguments filed 10/10/97 have been fully considered but they are not persuasive.

Applicant's arguments for patentability are based on the fact that the cytokine was administered orally. Applicant claims that this is unexpected because prior art indicates that orally administered IFN had no

significant effect. Also, applicant argues that Cummins in his patent stipulates that the administration be targetted to oral and pharyngeal mucosa. Cummins teaches oral administration. That the cytokine was not absorbed by the oral and pharyngeal mucosa in the present invention has not been established by the specification. If this is an unexpected result, such is not established by the specification either. Neither does the specification show that the cytokine was swallowed with little or no contact with the oropharnyx region. On the contrary, see example 18 for instance. It has been well established that any advantage relied upon to urge patentability of an invention should be set forth in the specification. *Graham v. John Deere Co.*, 148 USPQ 459 (USSC 1966), *General Tire & Rubber Co. v. Jefferson Chemical Co.*,182 USPQ 70 (CA 2 1974). As long as Cummins shows oral administration and the instant specification and claims recite the same thing, then without more in the specification, it is to be assumed and it is inherent, that there was absorption by the oropharyngeal region. Although there may be a patentable difference between Cummins and the instant invention, applicant has failed to establish clear and convincing evidence that there is a patentable difference.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

NOTE

Any inquiry concerning this communication should be directed to Examiner **C. Sayala** at **Group 1302,** telephone number (703) 308-3035. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651. The fax phone number for this Group is (703)305-3601.

C Sayala
CHHAYA D. SAYALA
PRIMARY EXAMINER
GROUP 1300